

CLEAN SET OF ALL PENDING CLAIMS

1. A sterile flexible bone sheet for use during the in vivo replacement or reformation of preselected portions of an animal skeletal system comprising a continuous integral unitary sheet of demineralized natural bone with a cortical layer and a cancellous layer, the thickness of said sheet ranging from 2.0mm to 8.0mm, the sheet being capable of being bent from its original shape to conform to the configuration of a skeletal region to be repaired without damage to the sheet, said sheet being capable of inducing osteogenesis at the skeletal region.
2. A sterile flexible bone sheet according to claim 1 wherein the thickness of said sheet ranges from 2.0mm to 6.0mm.
3. A sterile flexible bone sheet according to claim 1 wherein the thickness of said cortical layer ranges from 1mm to 4mm and the thickness of said cancellous layer ranges from 1mm to 4mm.
4. A sterile flexible bone sheet according to claim 1 wherein said sheet [includes] has from 1% to 5% hyaluronic acid by weight.
5. A sterile flexible bone sheet according to claim 1 wherein said cortical and said cancellous bone comprises from 99% to 95% by weight of the bone sheet.
6. A sterile flexible bone sheet according to claim 1 wherein said cortical layer interfaces with said cancellous layer through a cortical cancellous section.
7. A sterile flexible bone sheet according to claim 1 wherein said demineralized sheet has residual calcium ranging from 3.0% to 8.0% by weight of the demineralized bone mass.
8. A sterile flexible bone sheet according to claim 1 wherein said demineralized sheet has a neutral pH.

9. A sterile flexible bone sheet according to claim 1 wherein said demineralized bone sheet has an osmolality ranging from 290mmol/kg to 310mmol/kg.

10. A sterile flexible bone sheet according to claim 1 wherein said cortical cancellous bone sheet comprises from 99% to 95% by weight of the demineralized bone and from 1% to 5% by weight from a group consisting of hyaluronic acid, sodium hyaluronate and derivations thereof.

11. A sterile flexible bone sheet according to claim 1 wherein said cortical cancellous bone sheet is cut from tibial allograft tissue.

12. A sterile flexible bone sheet according to claim 1 wherein said cortical cancellous bone sheet is cut from femoral allograft tissue.

13. A sterile flexible bone sheet according to claim 1 wherein said cortical cancellous bone sheet is cut from pelvic allograft tissue.

14. A sterile flexible bone sheet according to claim 1 wherein said cortical cancellous bone sheet is cut from cancellous allograft tissue.

15. A sterile flexible bone sheet for use during the in vivo replacement or reformation of preselected portions of a human bone comprising a continuous unitary sheet of demineralized natural bone including a cortical portion and a cancellous portion with the thickness of said bone sheet ranging from 2.0mm to 6.0mm, said sheet having hyaluronic acid or derivatives thereof with a molecular weight over 700,000 Daltons added thereto at a concentration of 1.0 to 4.0 mg/ml, said sheet being flexible for application to a bone to be repaired without damage to the sheet, said sheet being capable of inducing osteogenesis at the bone region.

16. A sterile flexible bone sheet according to claim 15 wherein the thickness of said cortical portion ranges from 1mm to 3mm and the thickness of said cancellous portion ranges from

1mm to 3mm.

17. A sterile flexible bone sheet according to claim 15 wherein said demineralized sheet has residual calcium ranging from 3.0% to 8.0% by weight of the demineralized bone mass.

18. A sterile flexible bone sheet according to claim 15 wherein said demineralized sheet has a neutral pH.

19. A sterile flexible bone sheet according to claim 15 wherein said demineralized bone sheet has an osmolality ranging from 290mmol/kg to 310mmol/kg.

20. A sterile flexible bone sheet according to claim 15 wherein said demineralized bone sheet comprises from 99% to 95% by weight of the demineralized cortical cancellous bone.

21. A sterile flexible bone sheet according to claim 15 wherein said cortical layer interfaces with said cancellous layer through a cortical cancellous section.

22. A sterile flexible bone sheet according to claim 15 wherein said cortical cancellous bone sheet is cut from tibial allograft tissue.

23. A sterile flexible bone sheet according to claim 15 wherein said cortical cancellous bone sheet is cut from femoral allograft tissue.

24. A sterile flexible bone sheet according to claim 15 wherein said cortical cancellous bone sheet is cut from pelvic allograft tissue.

25. A sterile flexible bone sheet according to claim 15 wherein said cortical cancellous bone sheet is cut from cancanal allograft tissue.

26. A sterile flexible bone sheet according to claim 15 wherein said sheet has a width and length ranging from 1-20cm.

27. A sterile flexible bone sheet for use during the in vivo replacement or reformation of

preselected portions of a human bone comprising a continuous unitary sheet of demineralized natural bone with a cortical layer and a cancellous layer with a cortical/cancellous interface, the thickness of said sheet comprising a cortical layer ranging in thickness from 1mm to 3mm and a cancellous layer ranging in thickness from 1mm to 3mm, the sheet being capable of being bent from its original shape to conform to the configuration of a bone to be repaired without damage to the sheet, said sheet being capable of inducing osteogenesis at the bone region.

28. A sterile flexible bone sheet according to claim 27 wherein said cortical cancellous bone sheet is cut from tibial allograft tissue.

29. A sterile flexible bone sheet according to claim 27 wherein said cortical cancellous bone sheet is cut from femoral allograft tissue.

30. A sterile flexible bone sheet according to claim 27 wherein said cortical cancellous bone sheet is cut from pelvic allograft tissue.

31. A sterile flexible bone sheet according to claim 27 wherein said cortical cancellous bone sheet is cut from cancellous allograft tissue.

32. A sterile flexible bone sheet for use during the in vivo replacement or reformation of preselected portions of an animal skeletal system comprising of a continuous unitary sheet of demineralized natural bone with a cortical layer and a cancellous layer with a cortical cancellous interface, said demineralized bone having a residual calcium weight ranging from 3.0% to 8.0% by weight of the demineralized bone mass with the thickness of said sheet ranging from 2.0mm to 8.0mm, said sheet containing buffered hyaluronic acid or a derivative of same with a molecular weight over 700,000 Daltons and having a neutral pH, the bone sheet being capable of being bent from its original shape to conform to the configuration of bone to be repaired without damage to the sheet,

said sheet being capable of inducing osteogenesis at the bone region.

33. A sterile flexible bone sheet for use during the in vivo replacement or reformation of preselected portions of a human bone comprising a continuous unitary sheet of demineralized natural bone with a cortical layer, a cancellous layer and a cortical cancellous interface said demineralized natural bone having a residual calcium ranging from 3.0% to 8.0% by weight of the demineralized bone mass with the thickness of said sheet ranging from 2.0mm to 6.0mm, said sheet containing therein, a hydrogel taken from a group consisting of hyaluronic acid, sodium hyaluronate or derivatives thereof with a molecular weight over 700,000 Daltons and having a neutral pH with an osmolality of 290mmol/kg to 300mmol/kg, the sheet being capable of being bent from its original shape to conform to the configuration of a bone to be repaired without damage to the sheet, said sheet being capable of inducing osteogenesis at said bone to be repaired.

34. A method of making a bone sheet with cortical and cancellous portions comprising:

- a). cutting a human bone into substantially tubular portions;
- b). cleaning marrow, blood and lipids from said tubular cut human bone;
- c). cutting said cleaned tubular bone longitudinally along its length;
- d). demineralizing said cut tubular bone rendering the same flexible; and
- e). pulling the ends of said bone formed by said longitudinal cut apart to form a bone sheet with cortical and cancellous portions.

35. A sterile flexible bone sheet according to claim 34 including the step of adding 1% to 5% hyaluronic acid by weight to the bone sheet.

36. A sterile flexible bone sheet according to claim 34 wherein said sheet is demineralized to have residual calcium ranging from 3.0% to 8.0% by weight of the demineralized bone mass.

37. A sterile flexible bone sheet according to claim 34 wherein said demineralized sheet has a neutral pH.